EXHIBIT 17

Infant inclined sleep product safety: A model for using biomechanics to explore safe infant product design

Junsig Wang [a], Safeer F. Siddicky [a,c], John L. Carroll [b], Brien M. Rabenhorst [a], David B. Bumpass [a], Brandi N. Whitaker [b], Erin M. Mannen [a,c,*]

[a] Department of Orthopaedic Surgery, University of Arkansas for Medical Sciences, Little Rock, AR, United States
[b] Department of Pediatrics, University of Arkansas for Medical Sciences, Little Rock, AR, United States
[c] Mechanical and Biomedical Engineering Department, College of Engineering, Boise State University, Boise, ID, United States

ARTICLE INFO

ABSTRACT

Over 450 adverse incidents have been reported in infant inclined sleep products over the past 17 years, with many infants found dead in both the supine and prone positions. The unique design of inclined sleep products may present unexplored suffocation risks related to how these products impact an infant's ability to move. The purpose of this study was to assess body movement and muscle activity of healthy infants when they lie supine and prone on different inclined sleep products. Fifteen healthy full-term infants (age: 17.7 ± 4.9 weeks) were recruited for this IRB-approved study. Three inclined sleep products with unique features, representative of different sleeper designs, were included. Surface electromyography (EMG) was recorded from infants' cervical paraspinal, abdominal, and lumbar erector spinae muscles for 60 s during supine and prone positioning. Neck and trunk sagittal plane movements were evaluated for each testing condition. Paired t-tests and Wilcoxon signed-rank tests were performed to compare each inclined sleeper to a flat crib mattress ($0°$ baseline condition). During prone positioning, abdominal muscle activity significantly nearly doubled for all inclined sleep products compared to the flat crib mattress, while erector spinae muscle activity decreased by up to 48%. Trunk movement significantly increased compared to the flat crib mattress during prone lying. During prone lying, inclined sleep products resulted in significantly higher muscle activity of the trunk core muscles (abdominals) and trunk movement, which has the potential to exacerbate fatigue and contribute to suffocation if an infant cannot self-correct to the supine position.

1. Introduction

The American Academy of Pediatrics (AAP) has highlighted the safe sleep environment to reduce the risk of sleep-related infant deaths since 1992. After the implementation of the "Back-to-Sleep"(currently "Safe-to-Sleep") campaign in 1992, the rate of Sudden Infant Death Syndrome (SIDS) has seen a substantial decrease (American Academy of Pediatrics,1992). However, the safe sleep environment is of continued public concern due to a plateau in the rate of SIDS incidence in recent years (Moon et al.,2016). In fact, about 3,500 sleep-related infant death cases were reported in a single year in 2013, which includes SIDS, ill-defined death, and accidental suffocation in bed (Matthews et al.,2015). The AAP recommendations for safe sleep include supine positioning, a firm sleep surface, and the avoidance of soft bedding. Previous studies have indicated that a baby crib with a firm mattress likely reduces the risk of infant suffocation (Kemp et al.,1998, 1994;Scheers et al.,2003). However, there are many tragic cases of SIDS that occur in commercial sleep products that may not comply with the AAP's recommendations for safe sleep.

Over the last decade, the relatively new class of "inclined sleep products" have been increasingly popular with parents and caregivers. According to the voluntary ASTM International standard (ASTM F3118-17a, 2017), an inclined sleep product is defined as $10°$ to $30°$ from the horizontal for seat back incline with seat back length < 432 mm and side height < 252 mm. Parents are advised to use restraints in the products to keep infants in a supine position and to discontinue use once an infant has the ability to roll over. This indicates that the design of infant inclined sleep products may have more risks if an infant finds themselves prone in the product. Between 2005 and 2019, 451 incidents associated with inclined sleep products were reported to the United States

Consumer Product Safety Commission (CPSC) (Consumer Product Safety Commission, 2019). Among 70 cases reviewed in detail, about 36% of dead infants found were prone in the inclined sleep products, implying that suffocation was apparently the cause of death. However, it was reported that some parents had never observed their infant roll from supine to prone, yet the infants were found prone, indicating that accidental rolls from supine to prone occurred in the inclined sleep products. The average age of infants found prone in the products was 4.2 months, and previous research suggests that only 25% of infants are able to roll from supine to prone at a mean age of 4.2 months (Nelson et al,2004).

Our recently published research on the same participants in this current study investigated the effect of different incline angles of crib mattresses (0° vs 10° vs. 20°) during supine and prone positioning. Incline angle is an isolated factor in the context of inclined sleep product design (Wang et al.,2020). We found increased muscle activity of the trunk abdominal muscles during prone positioning, and increased neck movement during supine positioning as the incline angle increased. While our previous study focused on the incline angle of a crib mattress, inclined sleep products feature varying characteristics such as plush materials, conforming designs, seat features, and curved surfaces, all which present a mechanical environment different than a firm and flat inclined crib mattress. Thus, the effect of different designs of inclined sleep products on muscle activity and an infant's ability to move have not been explored with regard to safe sleep. Understanding infant motion and muscle activity patterns to identify biomechanical characteristics associated with the risks of infant suffocation when infants are placed into different designs of inclined sleep products may provide insight into safe infant product designs.

The purpose of this study was to assess muscle activity and upper body movement of normal healthy infants when placed in three different inclined sleep products during prone and supine positioning compared to a 0° baseline crib mattress condition. We hypothesized that: (1) abdominal muscle activity would be increased while cervical paraspinal and lumbar erector spinae muscle activity would be decreased in inclined sleep products and (2) neck and trunk movement would be increased in inclined sleep products compared to a flat surface during prone positioning.

2. Methods

2.1. Participants

Fifteen healthy full-term infants (age: 17.7 ± 4.9 weeks; 8 M/7F; length: 61.5 ± 4.1 cm; weight: 6.5 ± 1.0 kg) were enrolled with parental permission. Caregivers of potential participants were recruited via flyers, and phone screen interviews were performed to see if their infant would qualify for the study approved by the institutional review board of the University of Arkansas for Medical Sciences. Infants were excluded if they had any diagnosed orthopaedic, developmental, or neurological conditions, or had received vaccinations within two weeks prior to data collection. Infants included in the study were born > 37 weeks gestation and were between the 5th and 95th percentile in height and weight (CDC.gov,2001).

2.2. Experimental procedure

2.2.1. Product selection

Three inclined sleep products that featured unique designs were included in the study. Each of them was evaluated using standard methodology for infant inclined sleep product and a hinged infant weight gage recommended by ASTM International (Fig. 1; Table 1) (ASTM F3118-17a,2017). Products varied in surface firmness, surface curvature, material composition or soft goods, and product dimensions. Incline angles at head ranged from 24.4°–31.3°, while angles at the thigh ranged from 24.3°–51.7°, representing significant seat design differences. Width at shoulder ranged from 39.7 to 47.3 cm, and width at hinge ranged from 39.7 to 47.2 cm. The support surface of the product was one of the more obvious design differences, with one product featuring thick rigid plastic molding (*product a*) and the others with no plastic molding (*products b and c*). Material selections or soft goods in the products were just as broad and included thick padding (*products a and c*), mesh (*products a and b*), or a combination (*products a and b*). Details about the included sleep products are presented in Table 1.
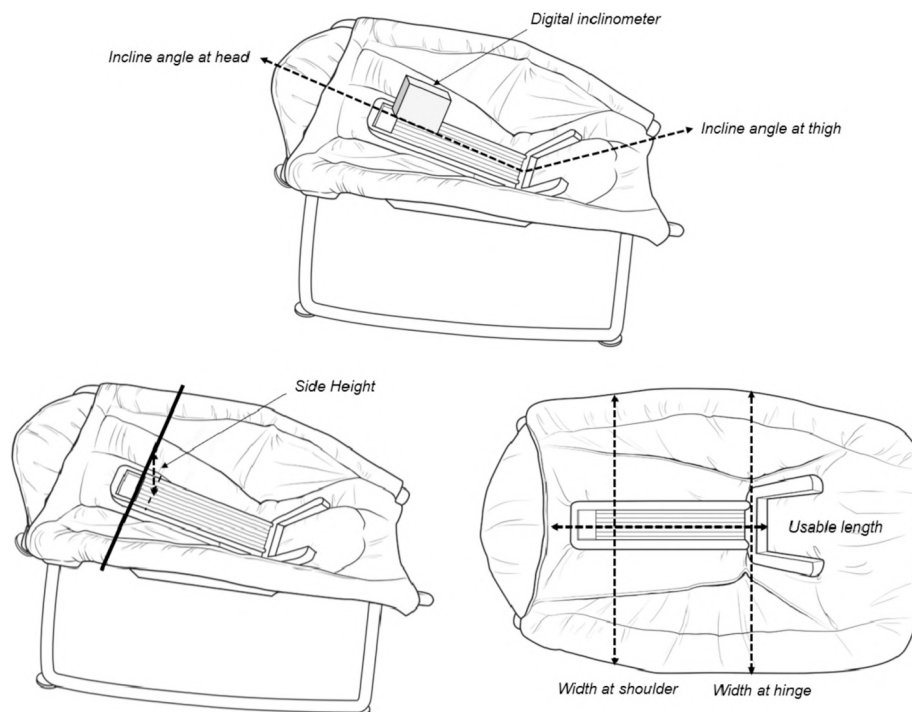

Fig. 1. Detailed measurements in a representative inclined sleep product using a hinged weight gage infant.

Table 1
Sleep product measurement and characteristics.

	Inclined angle at head/thigh (deg)	Side height (cm)	Usable length (cm)	Width at shoulder/hinge (cm)	Curved/thick plastic molding? (Y/N)	Thin plastic molding? (Y/N)	Side mesh? (Y/N)
product a	24.4/51.7	14.0	45.1	47.3/47.2	Y	N	Y
product b	25.5/24.3	17.1	43.5	39.7/39.7	N	N	Y
product c	31.3/38.2	9.7	43.5	42.9/40.6	N	N	N

	Inclined sleep product measurement notes	Product photo
product a	- Removable solid plastic molding - Depth at hinge = 25.4 cm – Deepest of all the products - Removable head pillow - Removable body cushion - Built-in vibration electronics - Removable toy on harness - Solid headrest - Detachable top portion	
product b	- No plastic molding - No rocking motion - Flaps to cover buttons - Mesh at head only	
product c	- No plastic molding - Compact product - Detachable head - Non-detachable head pillow - Embedded electronics under foot end - No mesh	

2.2.2. Testing conditions

The infant participants wore a disposable diaper only while room temperature was set at 24 °C. Infants were placed both supine and prone within the crib at 0° and within three sleep products (Fig. 2) for 60 s in each condition. Marker and EMG data were collected while infants were awake and not crying. Infants were unsecured the products to represent an unconstrained position. The order of the conditions was randomized, and a total of 8 trials (2 positions: supine and prone × 4 conditions:

Fig. 2. Photos of a-c) three inclined sleep products and d) flat mattress condition (0° baseline).

0° baseline and three sleep products) were performed while motion capture, electromyography, and oxygen saturation levels were collected.

2.2.3. Motion capture

Twenty-one *retro*-reflective markers were positioned on specific body segments (head, trunk, pelvis, and hand) and philtrum on the infant (Fig. 3). A motion analysis system with 10 high-resolution cameras (Vicon, Oxford, UK) was used to collect three-dimensional kinematic data (100 Hz). The marker data were used to calculate sagittal plane ranges of motion (ROMs) of the neck and trunk as well as the number of times the infants' trunks and necks were raised during each testing condition. Angular orientation between adjacent body segments was calculated by using the marker clusters on each body segment to define unit vector matrices forming the axes of local coordinate systems (Berthouze and Mayston,2011a; Wilk et al.,2006). The neck and trunk flexion/extension angular profiles were used in conjunction with a peak-finding algorithm (Yoder,2011) to calculate the number of times infants raised their head and trunk during each trial. The peak-finding algorithm swept through the angular profile data and isolated points in time where the angle value changed by 10° or more. The number of peaks is indicative of postural adjustments when infants performed a significant movement in the sagittal plane, which we postulate were required to lift the head and trunk off the surface to reposition or to facilitate breathing (Isono et al., 2004; Verin et al., 2002). The dependent kinematic variables include sagittal plane ROMs of the neck and trunk, as well as the number of sagittal plane neck and trunk angle peaks.

2.2.4. Electromyography

Surface EMG (Delsys Inc., Natick, MA; 1000 Hz) was recorded from the cervical paraspinal, abdominal, lumbar erector spinae, and triceps muscles during each testing condition. After excluding EMG data due to clipped amplitude, low power signal, or abnormal frequency pattern, EMG signals were filtered and rectified to obtain the EMG linear envelope (Boxtel,2001; Hodges and Bui, 1996; Siddicky et al.,2020b,2020a). The mean value of this linear envelope was calculated and normalized by the 0° baseline condition (supine or prone). All data analysis was conducted using custom MATLAB code. Triceps EMG data was excluded for the supine conditions since the hands and forearms were not in contact with the surface when babies were lying supine. EMG amplitudes were normalized by the 0° baseline condition (either during supine or prone lying) since maximal voluntary isometric contractions are impossible for infants to perform.

2.2.5. Oxygen saturation

Infants' oxygen saturation (SpO_2) during each testing condition was monitored in real-time using a medical grade pulse oximeter (PM10N; Covidien/Medtronic, Minneapolis, MN). A pulse oximeter sensor was placed on the right big toe and the onboard data logger recorded time-stamped SpO_2 data at 60 Hz (output at 1 Hz). For the safety of the participants, a trial was ended if SpO_2 was < 95% for 5 s.

2.2.6. Questionnaire

Caregivers were asked to complete an Ages and Stages Questionnaire (Squires et al., 2009) corresponding with the age of their infant to assess developmental progress, with focus on the Fine Motor and Gross Motor portions of the test. In addition, a pediatric developmental specialist (BNW), evaluated the movements of the infants via video of the biomechanical testing and provided a qualitative assessment of each infant's developmental progress based on head control, bilateral kicking and arm movements, hands to midline, kicking or arm movement in response to being spoken to, reaching for items, and loss of newborn reflexes. No infants were excluded from testing or analysis based on the results of the developmental screenings, which indicated all gross and fine motor skills were in the appropriate developmental range and infants were considered to be normally developing.

2.3. Statistical analyses

The nature of infant biomechanics research requires prioritization of the most important testing conditions while also balancing the experimental necessity of condition order randomization. This subset of three products was part of a larger study, where the baseline 0° condition was always prioritized and completed for each participant, and a minimum of six of eight testing conditions were completed by every participant. Although a statistical design to compare between products would be optimal, the limitations inherent to infant biomechanics research made
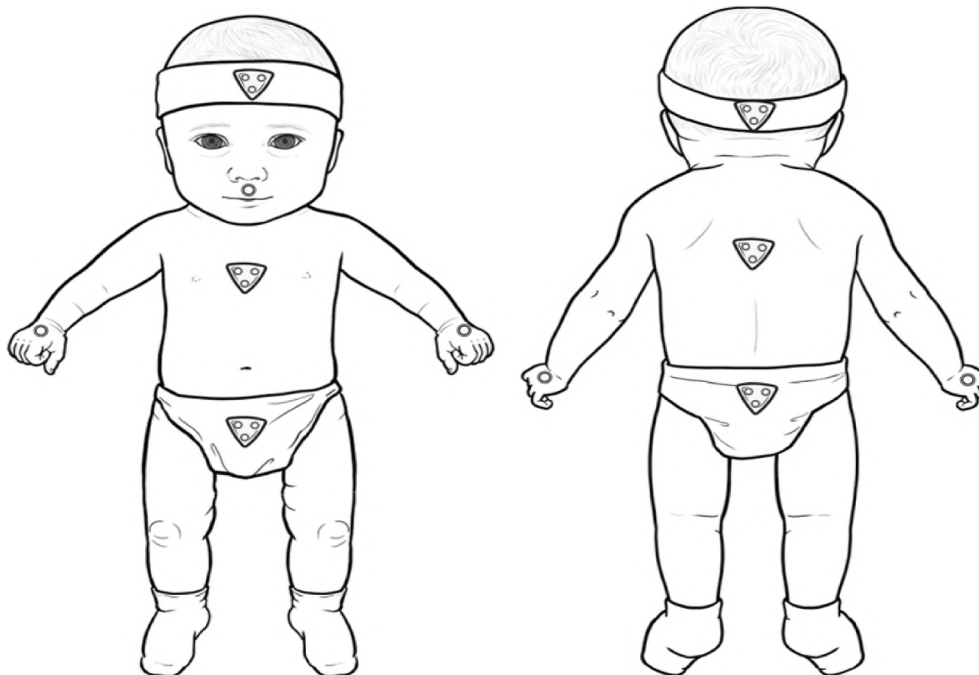

Fig. 3. Front and back view of marker location on infants.

this option unavailable. Because every participant completed the baseline 0° condition and this condition represents the AAP's recommended sleep surface, all data were therefore compared with the baseline 0° mattress condition, either during supine or prone lying. Paired t-tests and Wilcoxon signed rank tests for non-normally distributed variables were performed using SPSS (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). The level of statistical significance for all tests was set at $p < 0.05$.

3. Results

Testing was stopped for 10 total prone trials due to $SpO_2 < 95\%$ which is considered an abnormally low value (Vold et al.,2012) before the 60-second data collection was completed (one trial for 0° baseline; three trials for each product condition: *products a, b,* and *c*), yet only 2 of the 10 trials were excluded from analysis since those 2 trials (0° baseline and *product c*) did not meet the minimal duration of data collection (30 s) for data analysis. Therefore, all but two trials were included in further analysis. After data reconciliation (excluding corrupted, missing, or incomplete data), usable kinematic and EMG data were extracted for at least 10 participants for each of the inclined sleeper conditions.

3.1. Supine positioning

For supine positioning, the trunk angle peaks were significantly decreased for all sleep product conditions (*products a, b,* and *c*) as compared to the flat crib mattress ($p = 0.029$, $p = 0.016$, $p = 0.050$; Fig. 4). In addition, mean trunk flexion angles were significantly increased by 16.3°, 13.8°, and 10.9° when comparing the 0° flat crib mattress to *products a, b,* and *c* ($p = 0.007$, $p = 0.036$, $p = 0.001$). No significant changes in trunk or neck ROMs, number of neck angle peaks, and muscle activity variables were found between the flat surface and product conditions (Figs. 4 and 5).

3.2. Prone positioning

During prone positioning, significant differences in kinematic variables were found between the flat crib mattress and inclined sleep
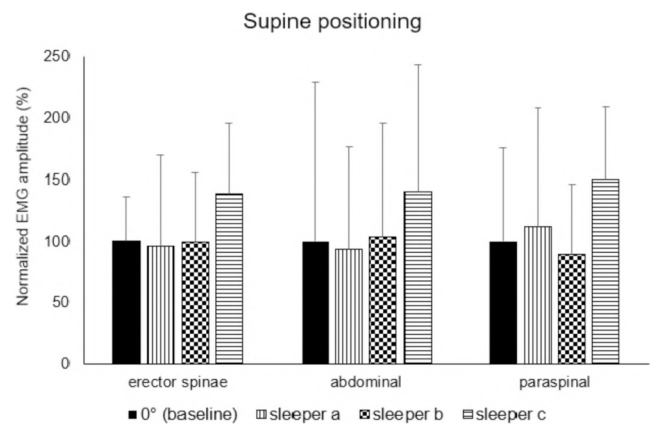

Fig. 5. Effect of different sleep product design on EMG activity during supine positioning. * indicates $p < 0.05$.

products (Fig. 6). Greater neck and trunk ROMs were found for *product b* compared to the flat crib mattress ($p = 0.014$, $p = 0.003$). In addition, the number of trunk angle peaks were increased for *products b,* and *c* compared to 0° baseline ($p = 0.047$, $p = 0.039$). For muscle activity, erector spinae activity decreased by 21%, 36%, and 48% respectively for *products a, b,* and *c* compared to the flat surface ($p = 0.050$, $p = 0.029$, $p = 0.003$; Fig. 7). Conversely, abdominal muscle activity increased by 75%, 39%, and 93% respectively for *products a, b,* and *c* as compared to the flat crib mattress ($p = 0.024$, $p = 0.029$, $p = 0.033$; Fig. 7). No significant differences in number of neck angle peaks, mean trunk extension angles, and paraspinal muscle activity were found between the flat crib mattress and product conditions during prone lying.

4. Discussion

The purpose of this study was to assess movement and muscle activity of infants placed within different inclined sleep products during prone and supine positioning, compared to a flat crib mattress (0° baseline condition).
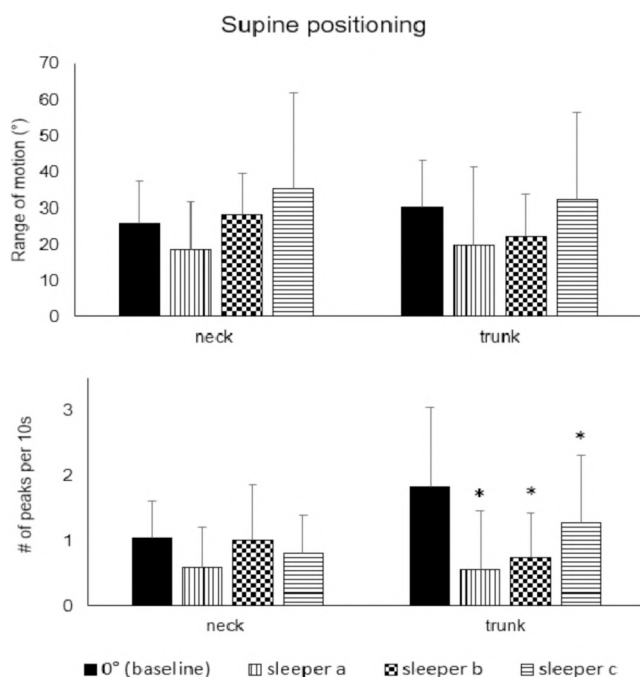

Fig. 4. Effect of different sleep product design on neck and trunk kinematic parameters during supine positioning. * indicates $p < 0.05$.
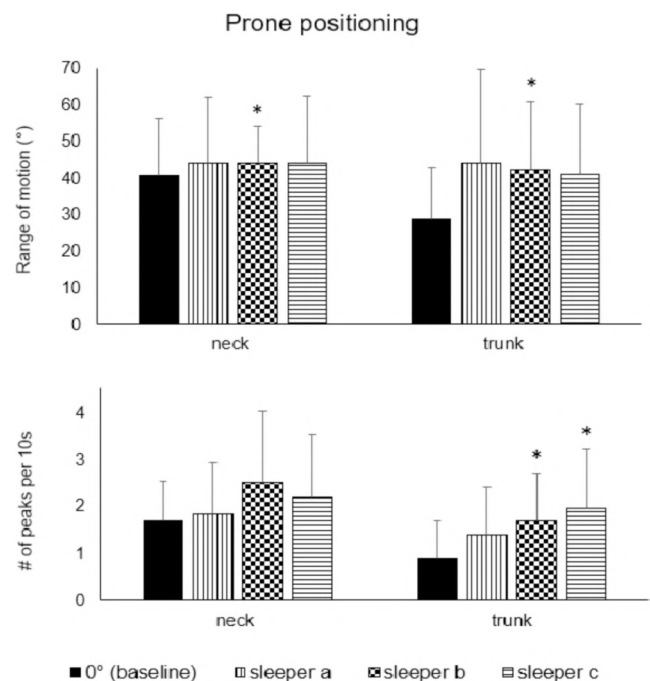

Fig. 6. Effect of different sleep product design on neck and trunk kinematic parameters during prone positioning. * indicates $p < 0.05$.
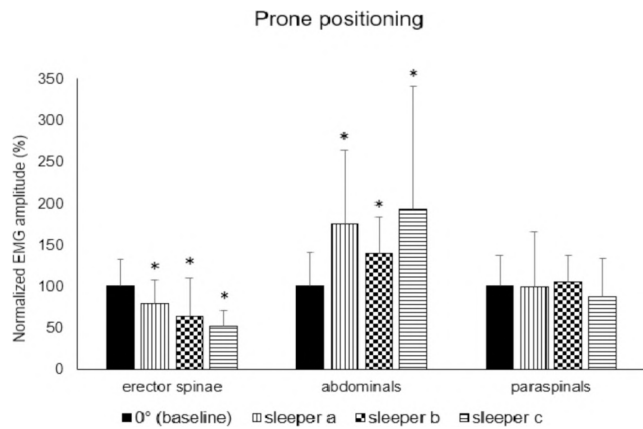
Fig. 7. Effect of different sleep product design on EMG activity during prone positioning. * indicates p < 0.05.

4.1. Supine positioning

Our results show no changes in neck and trunk ROMs in the inclined products compared to the flat surface during supine positioning. Infants also showed no differences in the number of times they lifted their heads in the inclined products, but they had significantly fewer trunk movements in the inclined products during supine lying. Conversely, we have previously demonstrated that increased incline angle of a flat crib mattress surface resulted in more neck motion and no changes in trunk motion (Wang et al.,2020). The difference in findings is likely due to a lack of surface firmness, increased curvature of the inclined sleep products, and the design feature of a seat compared to the inclined crib mattress from our previous study. Decreased trunk movement, even while infants were unsecured, was found in all types of inclined sleep products (various angles, plastic/ no plastic surfaces, various padding). When babies are positioned supine in inclined sleep products, positional conformity occurs, forcing the infant trunk into a more flexed position, up to 16.3° in the products examined in this study (likely due to the absence of firm support or due to heavy padding, or a combination of the two). Thus, the design of the inclined sleep products is promoting a more flexed spine, and preventing further trunk flexion during supine lying, in agreement with our results. Additionally, no changes in the neck and trunk muscle activity were found in the inclined products compared to the flat mattress surface. Because the babies are already in a flexed trunk position, further voluntary trunk flexion may be more difficult to achieve or may be impossible, leading to less sagittal plane trunk movement. However, we did not see this same phenomenon in the neck motion results, suggesting that although the trunk is unable to flex, the head is still able to experience ROMs similar to the flat crib mattress. We speculate that this flexed-trunk body position which renders additional trunk movement difficult, might explain the incidence of infants found in a chin-to-chest position as noted in some incident reports (Consumer Product Safety Commission, 2019). If the neck is the only available spinal segment for the infant to easily maneuver, the infants may rely on the head or lower extremities differently than if they were on a flat surface where the trunk was unconstrained and free to move.

A number of adverse incidents related to inclined sleep products were reported to the United States CPSC over the past several years. Specifically, some infants were found with their faces contacting the side of the inclined sleep product, and mucus or blood was found on infants' face, suggesting suffocation as the cause of death. The warning label on inclined sleep products suggests that parents should stop using the product once the infant can roll, possibly because inexperience of prone positioning results in decreased ability to avoid suffocation (Côté et al.,2000; Paluszynska et al.,2004). Although our findings showed infants moved less while lying supine in the sleep products, it should be noted that the flexed trunk position in combination with flexed hips due

to the design of the seat portion of the inclined sleep products (Table 1) puts babies closer to the fetal tuck position that is often used to achieve a supine to prone roll when compared to a flat crib mattress (Kobayashi et al.,2016). Thus, rolling from supine to prone is of particular concern when considering the design of inclined sleep products. Infants may not have to coordinate as many body segments to move synchronously in order to achieve a roll if they are already positioned in a flexed-hip posture facilitated by the seat design.

We previously observed that infants were not able to maintain a stable supine-lying posture at 30° inclined crib mattress surfaces due to sliding down the incline (Wang et al.,2020). So, inclined sleep products require a seat design feature to prevent infants from sliding at higher inclines. The combination of a steep incline and the seat feature subjects babies into a position that might more accurately be considered a reclined sitting posture rather than a lying posture. Other researchers have reported that changes in trunk posture impact pulmonary and respiratory function. For instance, Lin et al. found that a flexed trunk posture during sitting, not unlike the reclined flexed trunk sitting posture of the infants in our study, resulted in reduced lung capacity and lower expiratory flow compared to a normal standing posture (Lin et al.,2006). Another study demonstrated that slumped sitting posture altered ribcage configuration and chest wall movements compared normal sitting posture during breathing (Lee et al.,2010). Coupled with the common knowledge that infant breathing is not as robust as adult respiration, we speculate that body position likely influences breathing even more in infants compared to adults. In this sense, a flexed-trunk posture similar to the posture of the infants in the inclined sleep products likely puts infants at higher demand for pulmonary function that may lead to higher risk for suffocation.

4.2. Prone positioning

Inclined sleep products resulted in different movement patterns of neck and trunk during prone positioning, compared to a flat crib mattress surface. Neck and trunk ROMs tended to increase for the inclined product conditions compared to the flat mattress but only *product b* showed significant increases in neck and trunk ROMs. It was noted that *product b* had no plastic surface and had relatively narrow width at the shoulder, which likely required infants to perform greater postural changes to maintain a safe position. Interestingly, products without any plastic surface support (*product b* and *c*) caused babies to move more often as they worked against the pliant surface to move their bodies compared to the firm and flat crib mattress. Only the product with a rigid plastic surface (*product a*) showed no difference in the number of times the babies lifted their trunk compared to prone lying on a flat crib mattress.

Infants used their abdominal muscles significantly more when lying prone in the inclined sleep products compared to the flat crib mattress surface. It should be noted that products with thick padding (*product a and c*) exhibited increases in abdominal muscle activity of 175% and 193%, respectively, compared the flat crib mattress condition. Additionally, one product without plastic molding (*product b*) showed 139% increased abdominal muscle activity. This supports the idea that the lack of firmness or the presence of extra padding in the sleep surface alters a baby's ability to move, which could contribute to the increased risk of suffocation if a baby struggles to move into a safe breathing position (Hauck et al.,2003; Kemp et al.,1994; Thach et al.,2007). These findings suggest that the combination of incline angle and product design requires infants to use significantly more core effort (abdominal strength) to maintain a prone position compared to lying on a flat surface. If an infant achieves a roll from supine to prone within an inclined sleep product, the limited horizontal space and pliant concave surface likely makes rolling prone to supine difficult or impossible. Therefore, infants attempt to maintain a safe prone posture to facilitate breathing, which places an increased demand on the core muscles as suggested by the EMG results.

Previous researchers have shown the critical role of abdominal muscles in breathing. Core muscles work to stabilize the chest wall, pushing up on the partially compressible abdominal contents. Contraction of the diaphragm then elevates and expands the lower rib cage, while also lowering intrathoracic pressure (Panitch,2015). This suggests that abdominal muscle activity is closely related to diaphragm function and thus, breathing (Cresswell et al.,1992). Core muscles also aid in exhalation against obstructed airways (Bishop,1963; Goldman et al.,1987). Goldman et al. found that differing neck angles from 10° flexion to 40° extension modified abdominal muscle activity due to diaphragm motion (Goldman et al.,1987). Others have discovered that contraction of core muscles may lead to decreased lung volume and hypoxia (Bolivar et al.,1995; Esquer et al.,2008,2007). It is likely that infants in the prone position within an inclined sleep product with increased abdominal muscle activity also have restricted rib cage expansion and may be at further risk for hypoxemia. However, the relationship between infant body position and breathing must be further explored.

4.3. Methodological considerations

The current study presented several challenges. Bony landmarks for marker placements were estimated since bones were not fully developed in infants. A method of using local coordinate systems on each body segment was applied to minimize the errors of lack of anatomical landmarks in babies (Berthouze and Mayston,2011b; Wilk et al.,2006). Sixty second samples of biomechanical data on fully awake infants in a laboratory setting may not ideally represent daily life. In most of the incidents we reviewed, infants were reportedly placed for a nap or for overnight sleep in the inclined sleep products. Experimental limitations did not allow for us to test infants while asleep, yet our results are still relevant considering infants experience periods of wakefulness even during overnight sleep. Furthermore, babies arouse from unsafe sleep environments less quickly during sleep compared to during wakefulness, so our study may underreport the dangers of the inclined sleep products in the context of suffocation risk. Surface EMG sensors have several inherent limitations, however, the sensors have been used in other recent infant studies (Price et al.,2018; Siddicky et al.,2020a, 2020b). Due to missing trials and small samples for the sleeper product conditions, we were not able to compare between the inclined sleep products. We did not correct for the multiple statistical analyses performed, which may result in inflated Type I errors. Future studies could seek to assess how individual characteristics such as firmness, curvature, conformity, and seat design of products impact an infant's biomechanics and ability to breathe. Lastly, this study did not take into consideration CO_2 rebreathing and sleep surface breathability which represent important pieces in the puzzle to understand and inform safety considerations for the infant sleep environment.

4.4. Conclusion

This study is the first to investigate the effect of different inclined sleep product designs on the muscle activity and movement of infants. During supine positioning in inclined sleep products, the trunk experienced increased flexion and limited movement, which is concerning for both breathing and the potential for chin-to-chest incidents compared to a flat crib mattress. During prone positioning, inclined sleep products required greater neck and trunk adjustments as well as increased muscle activity of trunk core muscle (abdominals), which are critical in performing the work of breathing. These findings indicate that infants are likely to fatigue faster when prone in inclined sleep products compared to a flat crib mattress due to the increased musculoskeletal demands necessary to maintain safe prone posture to prevent suffocation. The results of our novel study support the AAP's recommendation that a firm and flat surface without additional padding is best for an infant sleep environment to avoid suffocation-related deaths due in part to the

mechanical environment.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

American Academy of Pediatrics AAP Task Force on Infant Positioning and SIDS Positioning and SIDS., 1992. . Pediatrics 89, 1120–6. https://doi.org/10.1542/peds.2011-2285.

ASTM F3118-17a, 2017. Standard Consumer Safety Specification for Infant Inclined Sleep Products. https://doi.org/10.1520/F3118-17A.

Berthouze, L., Mayston, M., 2011. Design and validation of surface-marker clusters for the quantification of joint rotations in general movements in early infancy. J. Biomech. 44 (6), 1212–1215. https://doi.org/10.1016/j.jbiomech.2011.01.016.

Bishop, B., 1963. Abdominal muscle and diaphragm activities and cavity pressures in pressure breathing. J. Appl. Physiol. 18 (1), 37–42. https://doi.org/10.1152/jappl.1963.18.1.37.

Bolivar, J.M., Gerhardt, T., Gonzalez, A., Hummler, H., Claure, N., Everett, R., Bancalari, E., 1995. Mechanisms for episodes of hypoxemia in preterm infants undergoing mechanical ventilation. J. Pediatr. 127, 767–773. https://doi.org/10.1016/S0022-3476(95)70171-0.

Boxtel, A., 2001. Optimal signal bandwidth for the recording of surface EMG activity of facial, jaw, oral, and neck muscles. Psychophysiology 38 (1), 22–34. https://doi.org/10.1111/1469-8986.3810022.

CDC.gov, 2001. Growth Charts - Homepage [WWW Document]. URL https://www.cdc.gov/growthcharts/index.htm (accessed 5.8.20).

Consumer Product Safety Commission, C., 2019. Federal Register : Safety Standard for Infant Sleep Products.

Côté, A., Gerez, T., Brouillette, R.T., Laplante, S., 2000. Circumstances leading to a change to prone sleeping in sudden infant death syndrome victims. Pediatrics 106, E86. https://doi.org/10.1542/peds.106.6.e86.

Cresswell, A.G., Grundström, H., Thorstensson, A., 1992. Observations on intra-abdominal pressure and patterns of abdominal intra-muscular activity in man. Acta Physiol. Scand. 144, 409–418. https://doi.org/10.1111/j.1748-1716.1992.tb09314.x.

Esquer, C., Claure, N., D'Ugard, C., Wada, Y., Bancalari, E., 2008. Mechanisms of hypoxemia episodes in spontaneously breathing preterm infants after mechanical ventilation. Neonatology 94, 100–104. https://doi.org/10.1159/000116634.

Esquer, C., Claure, N., D'Ugard, C., Wada, Y., Bancalari, E., 2007. Role of abdominal muscles activity on duration and severity of hypoxemia episodes in mechanically ventilated preterm infants. Neonatology 92, 182–186. https://doi.org/10.1159/000102056.

Goldman, J.M., Lehr, R.P., Millar, A.B., Silver, J.R., 1987. An electromyographic study of the abdominal muscles during postural and respiratory manoeuvres. J. Neurol. Neurosurg. Psychiatry 50 (7), 866–869. https://doi.org/10.1136/jnnp.50.7.866.

Hauck, F.R., Herman, S.M., Donovan, M., Iyasu, S., Moore, C.M., Donoghue, E., Kirschner, R.H., Willinger, M., 2003. Sleep environment and the risk of sudden infant death syndrome in an urban population The Chicago infant mortality study. Pediatrics 111, 1207–1214.

Hodges, P.W., Bui, B.H., 1996. A comparison of computer-based methods for the determination of onset of muscle contraction using electromyography. Electroencephalogr. Clin. Neurophysiol. - Electromyogr. Mot. Control 101 (6), 511–519. https://doi.org/10.1016/S0921-884X(96)95190-5.

Isono, S., Tanaka, A., Tagaito, Y., Ishikawa, T., Nishino, T., 2004. Influences of head positions and bite opening on collapsibility of the passive pharynx. J. Appl. Physiol. 97 (1), 339–346. https://doi.org/10.1152/japplphysiol.00907.2003.

Kemp, J.S., Livne, M., White, D.K., Arfken, C.L., 1998. Softness and potential to cause rebreathing differences in bedding used by infants at high and low risk for sudden infant death syndrome. J. Pediatr. 132 (2), 234–239. https://doi.org/10.1016/S0022-3476(98)70437-8.

Kemp, J.S., Nelson, V.E., Thach, B.T., 1994. Physical properties of bedding that may increase risk of sudden infant death syndrome in prone-sleeping infants. Pediatr. Res. 36, 7–11. https://doi.org/10.1203/00006450-199407001-00002.

Kobayashi, Y., Watanabe, H., Taga, G., 2016. Movement patterns of limb coordination in infant rolling. Exp. Brain Res. 234 (12), 3433–3445. https://doi.org/10.1007/s00221-016-4741-2.

Lee, L.-J., Chang, A.T., Coppieters, M.W., Hodges, P.W., 2010. Changes in sitting posture induce multiplanar changes in chest wall shape and motion with breathing. Respir. Physiol. Neurobiol. 170 (3), 236–245. https://doi.org/10.1016/j.resp.2010.01.001.

Lin, F., Parthasarathy, S., Taylor, S.J., Pucci, D., Hendrix, R.W., Makhsous, M., 2006. Effect of different sitting postures on lung capacity, expiratory flow, and lumbar lordosis. Arch. Phys. Med. Rehabil. 87 (4), 504–509. https://doi.org/10.1016/j.apmr.2005.11.031.

Matthews, T., MacDorman, M., Thoma, M., 2015. Infant Mortality Statistics From the 2013 Period Linked Birth/Infant Death Data Set. Natl. Vital Stat, Rep, p. 64.

Moon, R.Y., Darnall, R.A., Feldman-Winter, L., Goodstein, M.H., Hauck, F.R., 2016. SIDS and other sleep-related infant deaths evidence base for 2016 updated recommendations for a safe infant sleeping environment. Pediatrics 138. https://doi.org/10.1542/peds.2016-2940.

Nelson, E.A.S., Yu, L.M., Wong, D., Wong, H.Y.E., Yim, L., 2004. Rolling over in infants age, ethnicity, and cultural differences. Dev. Med. Child Neurol. 46 (10) https://doi.org/10.1017/S0012162204001185.

Paluszynska, D.A., Harris, K.A., Thach, B.T., 2004. Influence of sleep position experience on ability of prone-sleeping infants to escape from asphyxiating microenvironments by changing head position. Pediatrics 114 (6), 1634–1639. https://doi.org/10.1542/peds.2004-0754.

Panitch, H.B., 2015. Pulmonary complications of abdominal wall defects. Paediatr. Respir. Rev. 16 (1), 11–17. https://doi.org/10.1016/j.prrv.2014.10.004.

Price, C., McClymont, J., Hashmi, F., Morrison, S.C., Nester, C., 2018. Development of the infant foot as a load bearing structure study protocol for a longitudinal evaluation (the Small Steps study). J. Foot Ankle Res. 11, 33. https://doi.org/10.1186/s13047-018-0273-2.

Scheers, N.J., Rutherford, G.W., Kemp, J.S., 2003. Where should infants sleep? A comparison of risk for suffocation of infants sleeping in cribs, adult beds, and other sleeping locations. Pediatrics 112, 883–889. https://doi.org/10.1542/peds.112.4.883.

Siddicky, S.F., Bumpass, D.B., Krishnan, A., Tackett, S.A., McCarthy, R.E., Mannen, E.M., 2020a. Positioning and baby devices impact infant spinal muscle activity. J. Biomech. 104, 109741. https://doi.org/10.1016/j.jbiomech.2020.109741.

Siddicky, S.F., Wang, J., Rabenhorst, B., Buchele, L., Mannen, E.M., 2020b. Exploring infant hip position and muscle activity in common baby gear and orthopedic devices. J. Orthop. 39 (5), 941–949.

Squires, J., Bricker, D., Clifford, J., Murphy, K., Hoselton, R., Potter, L., Mounts, L., Farrell, J., 2009. Ages & Stages Questionnaires ® A Parent-Completed Child Monitoring System THIRD EDITION ASQ-3TM CD-ROM.

Thach, B.T., Rutherford, G.W., Harris, K., 2007. Deaths and Injuries Attributed to Infant Crib Bumper Pads. J. Pediatr. 151 (3), 271–274.e3. https://doi.org/10.1016/j.jpeds.2007.04.028.

Verin, E., Sériès, F., Locher, C., Straus, C., Zelter, M., Derenne, J.-P., Similowski, T., 2002. Effects of neck flexion and mouth opening on inspiratory flow dynamics in awake humans. J. Appl. Physiol. 92 (1), 84–92. https://doi.org/10.1152/jappl.2002.92.1.84.

Vold, M.L., Aasebø, U., Hjalmarsen, A., Melbye, H., 2012. Predictors of oxygen saturation ≤95% in a cross-sectional population based survey. Respir. Med. 106 (11), 1551–1558. https://doi.org/10.1016/j.rmed.2012.06.016.

Wang, J., Siddicky, S.F., Carroll, J.L., Rabenhorst, B.M., Bumpass, D.B., Whitaker, B.N., Mannen, E.M., 2020. Do inclined sleeping surfaces impact infants' muscle activity and movement? A safe sleep product design perspective. J. Biomech. 111, 109999. https://doi.org/10.1016/j.jbiomech.2020.109999.

Wilk, B., Karol, L.A., Johnston, C.E., Colby, S., Haideri, N., 2006. The effect of scoliosis fusion on spinal motion a comparison of fused and nonfused patients with idiopathic scoliosis. Spine (Phila. Pa. 1976). 31, 309–14. https://doi.org/10.1097/01.brs.0000197168.11815.ec.

Yoder, N., 2011. PeakFinder [WWW Document]. Internet http://www.mathworks.com-/matlabcentral/fileexchange/25500.